

**REMARKS**

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the amendments and remarks and attachments previously submitted, which place the application in condition for allowance. The Examiner is thanked for the courtesies extended during the January 2, 2003 telephonic interview; and, a further interview is respectfully requested if any issue remains after this paper, as it is believed that this paper is consistent with matters discussed with the Examiner.

**I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 22-24 and 36-49 are pending. Claims 22, 48 and 49 are amended, and claims 25-35 are cancelled, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims are patentably distinct from the documents cited by the Examiner, and that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims and the remarks made herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments and remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for the amended recitation in the claims is found throughout the specification.

**II. OBJECTION TO THE SPECIFICATION**

The specification was objected to for not having an abstract. The objection is traversed. The addition of the abstract on the separate sheet attached hereto obviates the objection. Consequently, reconsideration and withdrawal of the objection are respectfully requested.

**III. THE REJECTIONS UNDER §112, FIRST PARAGRAPH, ARE OVERCOME**

Claims 22, 23, 28, 31-34, 38-43, 48 and 49 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing non-enabling subject matter. The Office Action contends that only limited forms of formula (I) have been shown to be effective for the claimed control, but not for all compounds or compound groups.

While Applicants respectfully disagree, the amendments to the claims render the rejection moot. More specifically, claim 22 is amended to parallel the subgenus recited in U.S. Patent Nos. 6,482,425 and 6,083,51 wherein rejections similar to these in the instant application, it is

believed, were overcome. Indeed, it is respectfully submitted that to the extent the Examiner asserts that due to reasons of enablement the claims must be limited to certain embodiments, the Examiner is admitting that for those embodiments the claims are nonobvious (e.g., surprising, unexpected). Accordingly, the amendments herein address the rejections under Sections 112 and 103 and overcome them, especially as, it is respectfully submitted, the Examiner cannot have it both ways: The Office Action cannot maintain that undue experimentation is required to practice all but certain embodiments and then assert that those embodiments are not surprising and unexpected. Again, to the extent the Office Action asserts that the claims need be limited pursuant to Section 112, the Office Action admits that the claims so limited are nonobvious; and, this paper places the case in condition for allowance.

Consequently, the Section 112, first paragraph, rejection should be reconsidered and withdrawn; and, such relief is respectfully requested.

#### **IV. THE REJECTIONS UNDER §103 ARE OVERCOME**

Claims 22, 23, 28, 31-36, 38, 39, 43, 48 and 49 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Cooper et al. '96, MEO et al., *Proc. Am. Assoc. Vet. Parasitol.* (41 Meet., 52, 1996), Mizutani et al., WO 9616544, and Dryden et al. '94. None of the documents, either alone or in combination, teaches, suggests or discloses the present invention; and, as discussed above, by the Section 112 rejection, the Office Action admits that the claimed embodiments that overcome the rejection are nonobvious.

Applicants' invention is directed to, *inter alia*, a method for eradicating fleas in domestic or accommodation premises of a domestic or laboratory mammal, comprising topically applying, at least monthly to a localized region having a surface area between 5 and 10 cm<sup>2</sup> on the domestic or laboratory mammal, a parasitically effective amount of a spot-on topical preparation comprising a veterinarian acceptable vehicle and a compound of Formula I. Indeed, the compound of Formula I is the subgenus that was found patentable in U.S. Patent Nos. 6,482,425 and 6,083,519.

During the January 2, 2003 telephonic interview with the Examiner, for which the Examiner is again thanked for the courtesies extended thereat, Applicants explained that the instant case goes back to a 1997 French priority application, and that it seems that the art did not recognize using topical applications to animals as a means for eradicating fleas from premises or

laboratories, especially as shown by the 1999 NY Times article that Applicants previously submitted, that tends to show then only recent recognition.

During the interview, the Examiner appeared to agree that as to previous applications of fipronil to animals, the art did not teach or suggest the invention.

In consideration of the above, and for the reasons of record, and for the reasons discussed herein, none of the cited documents, either alone or in combination, disclose or suggest such a method; and nor do they teach, suggest or motivate a skilled artisan to practice such a method. In this respect, too, the Examiner is respectfully reminded again that the present claims are method claims; and the preamble recitation of the present claims must be fully considered in assessing patentability. *See, e.g., Diversitech Corp. v. Century Steps Inc.*, 850 F.2d 675, 7 U.S.P.Q.2d 1315 (Fed. Cir. 1988); *In re Tuominen*, 671, F.2d 1359, 213 U.S.P.Q. 89 (C.C.P.A. 1982); *In re Bulloch et al.*, 604 F.2d 1362, 203 U.S.P.Q. 171 (C.C.P.A. 1979); *In re Szajna et al.*, 422 F.2d 443, 164 U.S.P.Q. 632 (C.C.P.A. 1970); *In re Waller et al.*, 366 F.2d 786, 151 U.S.P.Q. 185 (C.C.P.A. 1966); *Smith v. Bousquet*; 111 F.2d 157, 45 U.S.P.Q. 347 (C.C.P.A. 1940); *Ex parte Varga*, 189 U.S.P.Q. 204 (P.O.B.A. 1973); *see also Kropa v. Robie et al.*, 187 F.2d 150, 88 U.S.P.Q. 478 (C.C.P.A. 1951). When the preamble of the present claims is fully considered, it is clear that the art fails to teach or suggest the instant invention.

And the Examiner is respectfully further reminded of the case law; namely, that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, “obvious to try” is not the standard under 35 U.S.C. §103. *In re Fine*, 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): “The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification.” Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants’ disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

One of the unique features of Applicants’ invention is that fleas are eradicated from domestic or accommodation premises by applying the instant formulation as a spot-on onto the



domestic or laboratory mammal. None of the documents cited in the Office Action teach, recite, disclose or inherently suggest such an invention. Specifically, none of the cited documents teaches or suggests eradicating fleas from a premises; and, even the Examiner's Section 112 position refutes this rejection, because in the Section 112 rejection, the Examiner recognizes that the art does not teach or suggest eradicating fleas from the premises by topical application to a mammal. Further still, the Brody New York Times article shows that the present invention was not recognized until 1999, thereby again leading to the conclusion that the present invention cannot be rendered obvious by any of the documents relied upon by the Office Action, either alone or in combination.

Indeed, it cannot be argued that any of the documents inherently achieves flea eradication of the premises. It is not enough for one to contend that the compounds or methods in the relied-upon documents "inherently" speak to the instantly claimed invention. It is, in fact, not enough to simply "speculate," as the Office Action does, that the relied-upon documents "inherently" speak to the instantly claimed invention. Speculation is not enough. *See Rapoport v. Dement*, 59 U.S.P.Q.2d 1215 (Fed. Cir. 2001). The documents must disclose or suggest the properties for inherency to attach.

According to *In re Rijckaert*, 9 F.3d 1531, 1957 (Fed. Cir. 1993), "such a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection." The Federal Circuit is clear that "'inherency...may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient [to establish inherency].'" *Continental Can Company v. Monsanto Company*, 948 F.2d 1264, 1269 (Fed. Cir. 1991), *citing to In re Oelrich*, 666 F.2d 578, 581-582 (C.C.P.A. 1981).

Indeed, "before a reference can be found to disclose a feature by virtue of its inherency, one of ordinary skill in the art viewing the reference must understand that the unmentioned feature at issue is *necessarily* present in the reference." *SGS-Thomson Microelectronics, Inc. v. International Rectifier Corporation*, 31 F.3d 1177 (Fed. Cir. 1994) (emphasis in original).

Applying the law to the instant facts, none of the documents cited in the Office Action inherently teach, disclose or suggest Applicants' invention. That is, none of the documents inherently teach, disclose or suggest eradication of fleas in domestic or accommodation premises



by the spot-on application of the instant formulations on the mammal. Thus, inherency cannot attach.

Further, picking and choosing portions from four disparate references in order to formulate an obviousness rejection, it is respectfully submitted, is impermissible. "Obvious to try" is not the standard upon which an obviousness rejection can be based. *See In re Fine*. Applying the law to the instant facts, it is respectfully submitted the rejection is fatally defective and should be reconsidered and withdrawn.

Consequently, reconsideration and withdrawal of the Section 103(a) rejection is believed to be in order and such relief is respectfully requested.

**REQUEST FOR INTERVIEW**

If any issue remains as an impediment to allowance, an interview with the Examiner is respectfully requested, prior to issuance of any paper other than a Notice of Allowance; and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

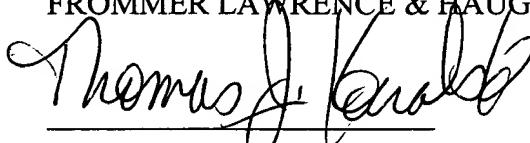
**CONCLUSION**

In view of the remarks and amendments herewith and those of record and the documents previously submitted, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance, or an interview at a very early date with a view to placing the application in condition for allowance, are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

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